

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sudhir V. Shah

Continuation Application of

Application No.: 09/553,496

Filed: April 20, 2000

Title: DIAGNOSIS AND TREATMENT OF HUMAN KIDNEY DISEASES

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| Date: <u>4/8/04</u> |
| EXPRESS MAIL LABEL NO. <u>EV052033004 US</u> |

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. 09/553,496, by Sudhir V. Shah, filed April 20, 2000, Docket No.: 2629.1003-003

____ U.S. Patent Application No. 10/731,522, by Sudhir V. Shah, filed December 9, 2003, Docket No.: 2629.1003-009

____ U.S. Patent Application No. 10/731,521, by Sudhir V. Shah, filed December 9, 2003, Docket No.: 2629.1003-010

____ By Sudhir V. Shah, filed April 8, 2004, Docket No.: 2629.1003-011

Examiner

Date

- [] A copy of each above-cited application, including the current claims, is enclosed.
- [X] A copy of each above-cited application, including the current claims, is enclosed, except U.S. Application No. 09/553,496, to which priority under 35 U.S.C. § 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

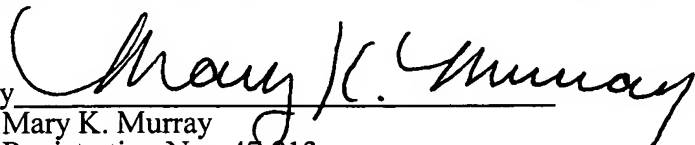
It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

Mary K. Murray
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Dated:

April 8, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
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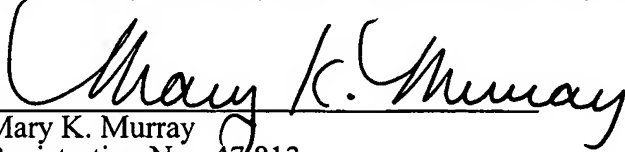
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Concord, MA 01742-9133

Dated: *April 8, 2004*

April 8, 2004

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
2629.1003-008

FIRST NAMED INVENTOR
Sudhir V. Shah

U.S. PATENT DOCUMENTS

| EXAM- INER INI- TIAL | REF. NO. | DOCUMENT NUMBER Number-Kind Code (if known) | ISSUE DATE / PUBLICATION DATE MM-DD-YYYY | NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT |
|-------------------------------|-------------|--|--|--|
| | AA | 5,047,421 | 09-10-91 | Green |
| | AB | 5,721,209 | 02-24-98 | Horwitz <i>et al.</i> |
| | AC | 5,811,127 | 09-22-98 | Milstein <i>et al.</i> |
| | AD | 5,091,180 | 02-25-92 | Walker <i>et al.</i> |

FOREIGN PATENT DOCUMENTS

[illegible]

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

April 8, 2004

(Use several sheets if necessary)

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2629.1003-008

FIRST NAMED INVENTOR
Sudhir V. Shah

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|-----|---|
| AR | Sumboonnanda, A., <i>et al.</i> , "Renal tubular function in β -thalassemia", <i>Pediatr Nephrol</i> , 12:280-283. |
| AS | Ong-ajyooth, L., <i>et al.</i> , "Renal Function in Adult Beta-Thalassemia/Hb E Disease", <i>Nephron</i> , 78:156-161 (1998). |
| AT | Guasch, A., <i>et al.</i> , "Evidence that Microdeletions in the α Globin Gene Protect Against the Development of Sick Cell Glomerulopathy in Humans", <i>J Am Soc Nephrol</i> , 10:1014-1019 (1999). |
| AU | Loebstein, R., <i>et al.</i> , "Diabetic Nephropathy in Hypertransfused Patients with β -Thalassemia", <i>Diabetes Care</i> , 21(8):1306-1309 (1998). |
| AV | Ongajyooth, L., <i>et al.</i> , "Glomerulonephritis in β -thalassemia Hb-E Disease: Clinical Manifestations, Histopathologic Studies and Outcome", <i>J Med Assoc Thai</i> , 78(3):119-126 (1995). |
| AW | Aoki, R.Y., <i>et al.</i> , "Microalbuminuria in Sick Cell Disease", <i>Brazilian J Med Biol Res</i> , 23:1103-1106 (1990). |
| AX | Katopodis, K.P., <i>et al.</i> , "Renal Abnormalities in Patients with Sick Cell-Beta Thalassemia", <i>Journal of Nephrology</i> , 10(3):163-167 (1997). |
| AY | Pham, P.-T.T., <i>et al.</i> , "Renal abnormalities in sickle cell disease", <i>Kidney International</i> , 57:1-8 (2000). |
| AZ | Kontoghiorghes, G.J., <i>et al.</i> , "Simple Synthesis of the Potent Iron Chelators 1-Alkyl-3-hydroxy-2-methylpyrid-4-ones", <i>Inorganica Chimica Acta</i> , 136:L11-L12 (1987). |
| AR2 | Falk, R.J., <i>et al.</i> , "Prevalence and Pathologic Features of Sick Cell Nephropathy and Response to Inhibition of Angiotensin-Converting Enzyme", <i>The New England Journal of Medicine</i> , 326(14):910-915 (1992). |
| AS2 | Guasch, A., <i>et al.</i> , "Sickle cell anemia causes a distinct pattern of glomerular dysfunction", <i>Kidney International</i> , 51:826-833 (1997). |
| AT2 | Cianciulli, P., <i>et al.</i> , "Early detection of nephrotoxic effects in thalassemic patients receiving desferrioxamine therapy", <i>Kidney International</i> , 46:467-470 (1994). |
| AU2 | Ueda, N., <i>et al.</i> , "Role of 'catalytic' iron in an animal model of minimal change nephrotic syndrome", <i>Kidney International</i> , 49:370-373 (1996). |

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| PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION April 8, 2004 (Use several sheets if necessary) | ATTORNEY DOCKET NO. 2629.1003-008 FIRST NAMED INVENTOR Sudhir V. Shah |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | |
|--|---|--|
| AV2 | Savill, J., <i>et al.</i> , "Mechanisms of glomerular injury". In "Oxford Textbook of Clinical Nephrology," 2 nd ed., pages 404-439, eds., Davidson, A.M., <i>et al.</i> , Oxford Univ. Press (1998). | |
| AW2 | Ueda, N., <i>et al.</i> , "In Vivo Evidence for a Role of Reactive Oxygen Metabolites in Glomerular Disease", <i>Kidney: A Current Survey of World Literature</i> , 6:143-146 (1997). | |
| AX2 | Boyce, N.W., <i>et al.</i> , "Hydroxyl radical mediation of immune renal injury by desferrioxamine", <i>Kidney International</i> , 30:813-817 (1986). | |
| AY2 | Baliga, R., <i>et al.</i> , "Kidney Iron Status in Passive Heymann Nephritis and the Effect of an Iron-Deficient Diet", <i>J Am Soc Nephrol</i> , 7(8):1183-1188 (1996). | |
| AZ2 | Shah, S.V., "Evidence suggesting a role for hydroxyl radical in passive Heymann nephritis in rats", <i>The American Physiological Society</i> , F337-F344(1988). | |
| AR3 | Thakur, V., <i>et al.</i> , "Evidence suggesting a role for hydroxyl radical in puromycin aminonucleoside-induced proteinuria", <i>Kidney International</i> , 34:494-499 (1988). | |
| AS3 | Nankivell, B.J., <i>et al.</i> , "The Role of Tubular Iron Accumulation in the Remnant Kidney", <i>J Am Soc Nephrol</i> , 4(8):1598-1607 (1994). | |
| AT3 | Alfrey, A.C., <i>et al.</i> , "Role of iron in the tubulo-interstitial injury in nephrotoxic serum nephritis", <i>Kidney International</i> , 36:753-759 (1989). | |
| AU3 | El Nahas, A.M., "Mechanisms of experimental and clinical renal scarring" In: "Oxford Textbook of Clinical Nephrology", 2 nd ed., pages 1749-1788, eds., Davidson, A.M., <i>et al.</i> , Oxford Univ. Press (1998). | |
| AV3 | Howard R.L., <i>et al.</i> , "Urinary albumin, transferrin and iron excretion in diabetic patients", <i>International Society of Nephrology</i> , 40:923-926 (1991). | |
| AW3 | Olivieri, N.F., <i>et al.</i> , "Iron-Chelation Therapy with Oral Deferiprone in Patients with Thalassemia Major", <i>The New England Journal of Medicine</i> , 918-922 (1995). | |
| AX3 | Alfrey A.C., "Toxicity of tubule fluid iron in the nephrotic syndrome", <i>American Journal of Physiology</i> , 263(4):F637-F641 (1992). | |

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| AY3 | Wu, Z-L, <i>et al.</i> , "Iron Loading Enhances Susceptibility to Renal Ischemia in Rats," <i>Renal Failure</i> , 16(4): 471-480 (1994). |
| AZ3 | Baliga, R., <i>et al.</i> , "In Vitro and In Vivo Evidence Suggesting a Role for Iron in Cistaplin-induced Nephrotoxicity," <i>Kidney International</i> , 53(2): 394-401 (February 1998). |
| AR4 | Harris, D., <i>et al.</i> , "Mitochondrial Function in Rat Renal Cortex in Response to Proteinuria and Iron," <i>Clinical and Experimental Pharmacology and Physiology</i> 24:916-922 (December 1997). |
| AS4 | Walker, P.D., <i>et al.</i> , "Evidence Suggesting a Role for Hydroxyl Radical in Gentamicin-Induced Acute Renal Failure in Rats," <i>J Clin Invest</i> 81:334-341 (1988). |
| AT4 | Shah, S.V., <i>et al.</i> , "Evidence Suggesting a Role for Hydroxyl Radical in Glycerol-Induced Acute Renal Failure," <i>Am J Physiol</i> 255, (<i>Renal Fluid Electrolyte Physiol.</i> 24):F438-F443 (1988). |
| AU4 | Baliga, R., <i>et al.</i> , "Increase in Bleomycin-Detectable Iron in Ischaemia/Reperfusion Injury to Rat Kidneys," <i>Biochem J</i> 291(3):901-905 (1993). |
| AV4 | Kontoghiorghese, G.J., <i>et al.</i> , "Studies of Aluminium Mobilization in Renal Dialysis Patients Using the Oral Chelator 1,2-Dimethyl-3-hydroxypyrid-4-one," <i>Arzneim-Forsch/Drug Res.</i> 44(1):522-526 (1994). |
| AW4 | Baliga, R., <i>et al.</i> , "Oxidant Mechanisms in Toxic Acute Renal Failure," <i>Drug Metabolism Reviews</i> 31(4):971-991 (1999). |
| AX4 | Walker, P.D., <i>et al.</i> , "Gentamicin Enhanced Production of Hydrogen Peroxide by Renal Cortical Mitochondria," <i>Am J Physiol</i> 253:C495-C499 (1987). |
| AY4 | Walker, P.D., <i>et al.</i> , "Hydrogen Peroxide Cytotoxicity in LLC-PK ₁ Cells: A Role for Iron," <i>Kidney Int</i> 40:891-898 (1991). |
| AZ4 | Abul-Ezz, S.R., <i>et al.</i> , "Role of Glutathione in an Animal Model of Myoglobinuric Acute Renal Failure," <i>Proc Natl Acad Sci</i> 88:9833-9837 (1991). |
| AR5 | Ueda, N., <i>et al.</i> , "Gentamicin-Induced Mobilization of Iron from Renal Cortical Mitochondria," <i>Am J Physiol</i> 265(3 Pt. 2):F435-F439 (1993). |
| AS5 | Baliga, R., <i>et al.</i> , "Evidence for Cytochrome P-450 as a Source of Catalytic Iron in Myoglobinuric Acute Renal Failure," <i>Kidney Int</i> 49:362-369 (1996). |

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| AU5 | Hanss, B.G., <i>et al.</i> , "The Iron Chelator Deferoxamine Prevents Contrast Media Induced Acute Renal Failure in the Rabbit." Presented at the American Society of Nephrology, 23 rd Annual Meeting, <i>JASN</i> 1(4):612 (1990) (abstract). |
| AV5 | Baliga, R., <i>et al.</i> , "Role of Iron in Cisplatin-Induced Acute Renal Failure in Rats," <i>J Am Soc Nephrol</i> 7(9):1822 (1996) (abstract). |
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